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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,266	01/27/2004	Reuel B. Van Atta	NX#26	3800
27489	7590	03/29/2006	EXAMINER	
RALPH T. LILORE 371 FRANKLIN AVENUE THIRD FLOOR - PO BOX 570 NUTLEY, NJ 07110			SHAW, AMANDA MARIE	
		ART UNIT	PAPER NUMBER	
			1634	

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/766,266	VAN ATTA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Amanda M. Shaw	1634

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-46 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-46 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. ____ .   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____ .                                   |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-22, drawn to probe sets used for detecting polymorphisms, classified in class 536, subclass 24.3.
  - II. Claims 23-46, drawn to methods for detecting polymorphisms, classified in class 435, subclass 6.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the probe set disclosed as Invention I can be used for other types of hybridization assays, or sequencing reactions.

### **Additional Requirements Applicable to Inventions I and II**

2. Further, should Applicants elect Invention I or Invention II, these groups are subjected to an additional restriction requirement as follows.

Claims 11, 15, 19, 33, 37, and 41 are subject to an additional restriction since these claims recite patentably distinct point mutations. Specifically, the claims are drawn to several distinct mutations that occur in different genes: G1691A in the Factor V gene (Claims 11 and 33), C187G in the HFE gene (Claims 15 and 37), and G845A in the HFE gene (Claims 19 and 41).

Each polymorphism is considered to patentably distinct since each polymorphism has a different effect on the gene in which it occurs in. Given the differences in the effect of each mutation, the patentably distinct mutations set forth in Claims 11, 15, 19, 33, 37, and 41 are subject to a further restriction requirement. A literature search for each of these mutations would not be co-extensive with one another. For example, a search for the mutation G1691A in the Factor V gene would not be coextensive with a search for the mutation C187G in the HFE gene. Similarly, a finding that the mutation G1691A in the Factor V gene is novel and unobvious over the prior art would not necessarily extend to a finding that the mutation C187G in the HFE gene is also novel and unobvious over the prior art. Accordingly, a search of more than one of the mutations presents an undue burden on the Patent and Trademark Office due to the complex nature of the search. Should the Applicant elect Invention I, they are required to elect one mutation selected from G1691A in the Factor V gene (Claim 11), C187G in the HFE gene (Claim 15), and G845A in the HFE gene (Claim 19). Should the Applicant elect Invention II, they are required to elect one mutation selected from G1691A in the Factor V gene (Claim 33), C187G in the HFE gene (Claim 37), and G845A in the HFE gene (Claim 41). Please note that whichever mutation is elected, the

corresponding probe set will also be examined. For instance if the applicant elects Invention I and the mutation G1691A (claim 11), then claims 12, 13, and 14 which depend from 11 will be examined. If the applicant elects Invention II and the mutation G845A in the HFE gene (Claim 41), then claims 42, 43, and 44 which depend from 41 will be examined.

3. In addition Claims 14, 18, 22, 36, 40, and 44 are subject to an additional restriction since these claims recite patentably distinct reporter probes. Specifically, the claims are drawn to several distinct reporter probes: SEQ ID NO: 6-12 (Claims 14 and 36), SEQ ID NO: 18-24 (Claims 18 and 40), and SEQ ID NO: 29-39 (Claims 22 and 44).

Each reporter probe consists of a different nucleotide sequence, has a different melting temperature, and a different specificity of hybridization. For example, a reporter probe comprising SEQ ID NO: 6 is chemically, structurally and functionally distinct from a reporter probe comprising SEQ ID NO: 12. A search for a reporter probe comprising SEQ ID NO: 6 would not be co-extensive with a search for a reporter probe comprising SEQ ID NO: 12. Further, a finding that a reporter probe comprising SEQ ID NO: 6, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that a reporter probe comprising SEQ ID NO: 12 is also novel and unobvious over the prior art. Accordingly if the applicant elects the mutation of Claim 11, they applicant must further elect one sequence from Claim 14 to be examined. If the applicant elects the mutation of Claim 33, they applicant must further elect one sequence from Claim 36 to be examined.

Note that this is not a species election.

4. For Invention I Claims 1-10 link the individual products of claims 11-22, that deal with patentably distinct mutations. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0

5. For Invention II Claims 23-32, and 45-46 link the individual methods of claims 33-44, that deal with patentably distinct mutations. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as exemplified by their different classification, restriction for examination purposes as indicated is proper. Further, a search for the inventions of both groups would not be co-extensive because a search indicating the process is novel or

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nonobvious would not extend to a holding that the product itself is novel or nonobvious; similarly, a search indicating that the product is known or would have been obvious would not extend to a holding that the process is known or would have been obvious.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be

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maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw  
Examiner  
Art Unit 1634  
March 21, 2006

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER